Why is the Johnson and Johnson vaccine being paused?

On 4/13/21, the Food and Drug Administration (FDA) and the Centers of Disease Control and Prevention (CDC) recommended a temporary pause in the use of the Johnson & Johnson (J&J) vaccine because 6 cases of a severe type of blood clot have been reported in people who received the vaccine in the US. The blood clot is called cerebral venous sinus thrombosis (CVST). The 6 cases were in women ages 18 to 48 and their symptoms started 6 to 13 days after they received the vaccine. These side effects are very rare. There have been almost 7 million doses nationally of the J&J vaccine administered in the U.S. and only 6 reported cases. The pause is being recommended out of an abundance of caution while the FDA and CDC complete their review of the cases. This is expected to take several days.

Why are they just finding out about this now?

The FDA authorized the Johnson & Johnson vaccine for use in the US after reviewing data, including the results of a phase 3 trial in which 21,895 people received the vaccine. The vaccine met the FDA's rigorous scientific standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization (EUA). New safety monitoring systems were added for the COVID-19 vaccines in addition to the routine monitoring that is done for all vaccines after they are in use. This is to find out about problems that might not be detected until the vaccine is in widespread use. The case reports of these rare blood clots were detected through the monitoring system called VAERS (the Vaccine Adverse Event Reporting System).

What symptoms should I look for? What do I do if I have symptoms?

If you received the J&J vaccine in the last 3 weeks, look for any symptoms of these unusual clots, including severe headaches, abdominal or leg pain, and shortness of breath. If you develop symptoms, contact your medical provider or seek medical care. If you don't have a medical provider, call 2-1-1 to be connected with a healthcare provider.

How should I report a side-effects from the vaccine?

If you experience side effects after any vaccine, please report them to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html.

Have there been any reports of these blood clots with the other vaccines?

As of April 13th, more than 180 million doses of Pfizer and Moderna have been administered in the United States with no reports of the cerebral venous sinus thrombosis (CVST) blood clots.

What do I do if I had an appointment for the Johnson and Johnson vaccine and it was canceled?

If you had an appointment for the Johnson & Johnson vaccine, your vaccine provider will contact you about rescheduling or providing a new appointment for Pfizer or Moderna vaccine.

